Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0921688	09/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Jackson Clinic,Pa North Internal, The	2863 Hwy 45 Bypass, Jackson, TN	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on observation of the microbiology laboratory, review of patient number one test report, proficiency testing records and interview with the laboratory supervisor, the laboratory failed to verify the accuracy of dermatophyte testing medium (DTM) fungal cultures in 2017 and 2018. The findings include: 1. Observation of the microbiology laboratory on September 10, 2018 at 10:00 am revealed DTM in use for performing patient fungal cultures. 2. Review of patient number one final test report revealed patient reporting for DTM on August 3, 2018. 3. Review of the laboratory's proficiency testing records for 2017 and 2018 revealed no records were available for twice a year verification of accuracy of DTM fungal culture in 2017 and 2018. 4. Interview with the laboratory supervisor on September 10, 2018 at 3:30 pm confirmed the laboratory did not verify the accuracy of DTM fungal cultures in 2017 and 2018.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test

	system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the manufacturer calibrator package insert, the manufacturer operator manual, calibration verification documents and interview with testing personnel number 2, the laboratory failed to verify the calibration of the glycated hemoglobin (hgb A1c) analyte on the Tosoh G8 instrument using at least a minimal, mid-point and maximum value near the upper limit of the range at least every 6 months in 2017 and 2018 with patients performed and reported. The findings include: 1. Observation of the laboratory on September 10, 2018 at 10:45 am revealed the Tosoh G8 instrument (serial #14676805) in use for patient testing for hgb A1c. 2. Review of the manufacturer hgb A1c calibrator package insert for lot ZS7001 revealed that calibration is performed using only 2 calibrators with calibrator values of 5.7% and 10.7%. 3. Review of the manufacturer operator manual for the Tosoh G8 instrument revealed a measuring range of 4.0% - 16.9% and calibration performed using only 2 calibrator levels for the hbg A1c analyte. 4. Review of calibration verification documents for the Hemoglobin A1c analyte revealed calibration verification was not performed every 6 months in 2017 or 2018. 5. Interview with testing personnel number one on September 11, 2018 at 10:00 am confirmed the laboratory performs patient testing for HGB A1c on the Tosoh G8 instrument, calibrates using 2 calibration points, uses the manufacturer measuring range, and failed to verify the calibration of the Tosoh G8 instrument every 6 months in 2017 and 2018 with patients performed and reported.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the prothrombin time (PT) calculated mean patient normal records, and interview with testing personnel number one, the laboratory failed to ensure the quality assessment (QA) process included the correct mean patient normal PT was correctly entered into the instrument in 2018. The findings include: 1. Observation of the laboratory on September 11, 2018 at 2:00 pm revealed the Sysmex CA620 in use for patient testing for PT. The mean patient normal PT entered into the instrument setting used for calculating the international normalized ratio (INR) was 10.3. 2. Review of the records for calculated mean patient

	normal PT for lot #549720 (current lot) revealed a mean patient normal PT value of 10.4. 3. Interview with testing personnel number one on September 11, 2018 at 2:20 pm confirmed the laboratory's QA was ineffective when the incorrect mean patient normal PT was entered into the coagulation instrument in 2018. There is no QA process to ensure the mean is entered into the instrument correctly.